



1043 '01 APR 13 P3:21
MAR 30 2001

Mr. Manoj Bhargava
Living Essentials
3141 Old Farm Lane
Walled Lake, Michigan 48390

Dear Mr. Bhargava:

This is in response to your letter of February 28, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Living Essentials is making the following claims for the product **Chaser**:

“Helps prevent hangovers”

“Helps prevent hangovers by absorbing elements in beer, wine and liquor that cause hangovers.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, mitigate a disease, namely, the consequences of excessive alcohol consumption. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the act. If you intend to make a claim of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "John B. Foret".

John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Chicago District Office, Office of Compliance, HFR-MW140

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cc:

HFA-224

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-810 (Foret)

HFS-811 (Moore, w/original incoming)

HFD-40 (Behrman)

HFD-310

HFD-3 14 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF- 1 (Nickerson)

r/d:HFS-81 1:RMoore:3/27/01

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Living Essentials

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February 28, 2001

Christine J. Lewis, Ph.D.
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

Dear Dr. Lewis,

We are sending you this letter in accordance with 21 CFR § 101.93(a)(1). Living Essentials, located at 3141 Old Farm Lane, Walled Lake, MI 48390 expects to distribute its dietary supplement product, tradenamed "Chaser," with the following statements:

- (1) "Helps prevent hangovers"
- (2) "Helps prevent hangovers by absorbing elements in beer, wine and liquor that cause hangovers."

The product contains vegetable carbon and activated calcium carbonate.

I hereby certify that this information is complete and accurate. Our firm has substantiation that the statements are truthful and not misleading.

Sincerely,

Manoj Bhargava

Manoj Bhargava

3141 Old Farm Lane, Walled Lake, MI 48390
Voice: (248) 960-1700 Fax: (248) 960-1980